

# UNITED STATES PATENT AND TRADEMARK OFFICE



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/424,431	03/16/2000	JOHN W WONG	287300022USA	7974	
75	90 03/26/2002				
THOMAS T MOGA HARNESS DICKEY & PIERCE PO BOX 828 BLOOMFIELD HILLS, MI 48303			EXAMINER		
			MENDOZA, N	MENDOZA, MICHAEL G	
			ART UNIT	PAPER NUMBER	
			3761		
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Please find below and/or attached an Office communication concerning this application or proceeding.



	Application No.	Applicant(s)				
Office Action Summary	09/424,431	WONG, JOHN W				
omeo Houen Gummary	Examiner	Art Unit				
The MAII ING DATE of this communication and	Michael G. Mendoza	3761				
The MAILING DATE of this communication app Period for Reply	ears on the cover sneet with the c	orrespondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status						
1) Responsive to communication(s) filed on 16 M	<u>larch 2000</u> .					
2a) This action is <b>FINAL</b> . 2b) ⊠ This	s action is non-final.					
3) Since this application is in condition for allowa	nce except for formal matters, pro	osecution as to the merits is				
closed in accordance with the practice under E Disposition of Claims	ex parte Quayle, 1935 C.D. 11, 4:	53 O.G. 213.				
4) $\boxtimes$ Claim(s) <u>1-20</u> is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-20</u> is/are rejected.						
7) Claim(s) is/are objected to.	7) Claim(s) is/are objected to.					
8) Claim(s) are subject to restriction and/or election requirement.						
Application Papers						
9) The specification is objected to by the Examiner.						
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.						
If approved, corrected drawings are required in reply to this Office action.  12) The oath or declaration is objected to by the Examiner.						
	miner.					
Priority under 35 U.S.C. §§ 119 and 120						
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) All b) Some * c) None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
<ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
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14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). a) ☐ The translation of the foreign language provisional application has been received.						
15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.						
Attachment(s)						
)   Notice of References Cited (PTO-892)	5) Notice of Informal Pa	PTO-413) Paper No(s) tent Application (PTO-152)				

U.S. Patent and Trademark Office PTO-326 (Rev. 04-01)

# **DETAILED ACTION**

Page 2

## Specification

This application does not contain an abstract of the disclosure as required by 37
 CFR 1.72(b). An abstract on a separate sheet is required.

# Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 3. Claims 1, 2, 3, 4, 5, 6, 7, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Rienmueller et al. 5,067,494.
- 4. As to claim 1, Rienmueller et al. teaches a method for delivering radiation therapy to a patient during suspended ventilation, the method comprising the steps of: identifying a specific air flow direction and lung volume (col. 2, lines 3-4); suspending patient ventilation at a specific air flow direction and lung volume (col. 2, lines 12-19); and administering radiation therapy during the suspension of patient ventilation (col.1, lines 63-65).
- 5. As to claim 2, Rienmueller et al. teaches a method for delivering radiation therapy to a patient during suspended ventilation according to claim 1, the method including the step of attaching a respiration monitor 6 to the patient through a mouth piece 9 that includes one or more air flow valves 14.

Art Unit: 3761

- 6. As to claim 3, Rienmueller et al. teaches a method for delivering radiation therapy to a patient during suspended ventilation according to claim 1, the method including the step of utilizing a computer control to provide a measure of the cyclical expiration and inhalation cycle of the patient (col. 3, lines 14-16).
- 7. As to claim 4, Rienmueller et al. teaches a method for delivering radiation therapy to a patient during suspended ventilation according to claim 2, the method including the step of operating the one or more air flow valves of the mouth piece to suspend the patient's breathing at a desired point (col. 2, lines 12-19).
- 8. As to claim 5, Rienmueller et al. teaches a method for delivering radiation therapy to a patient during suspended ventilation according to claim 4, the method including the steps of halting inhalation and exhalation during the time of suspended breathing (col. 2, lines 12-19).
- 9. As to claim 6, Rienmueller et al. teaches a method for delivering radiation therapy to a patient during suspended ventilation according to claim 1, the method including repeating the stop of suspending patient ventilation at a specific air flow direction and lung volume as necessary to administer repeated radiation doses (col. 1, line 26-35).
- 10. As to claim 7, Rienmueller et al. teaches a method for delivering radiation therapy to a patient during suspended ventilation according to claim 1,the method including undertaking CT planning and treatment at a reproducible ventilatory phase (col. 1, lines 26-35).

Application/Control Number: 09/424,431

Art Unit: 3761

Page 4

- 11. As to claim 9, Rienmueller et al. teaches a method for delivering radiation therapy to a patient during suspended ventilation according to claim 1, the method including the steps of acquiring CT scans at different respiratory phases (col. 1, lines 26-35).
- 12. Claims 10, 11, 12, 13, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Rienmueller et al.
- 13. As to claim 10, Rienmueller et al. teaches a method for establishing breath-holding reproducibility in a patient for the delivery of radiation therapy, the method comprising the steps of: identifying a lung volume (col.2 lines 8-9); suspending patient ventilation at a lung volume (col. 2, lines 12-19); and administering radiation therapy during the suspension of patient ventilation (col.1, lines 63-65).
- 14. As to claim 11, Rienmueller et al. teaches a method for establishing breath-holding reproducibility in a patient for the delivery of radiation therapy according to claim 10, the method including the step of attaching a respiration monitor to the patient through a mouthpiece 9 that includes one or more air flow valves 14.
- 15. As to claim 12, Rienmueller et al. teaches a method for establishing breath-holding reproducibility in a patient for the delivery of radiation therapy according to claim 11, the method including the step of operating the one or more air flow valves of the mouthpiece to suspend the patient's breathing at a desired point (col. 2, lines 12-19).
- 16. As to claim 13, Rienmueller et al. teaches a method for establishing breath-holding reproducibility in a patient for the delivery of radiation therapy according to claim

Art Unit: 3761

- 10, the method including the steps of halting inhalation and exhalation during the time of suspended breathing (col. 2, lines 12-19).
- 17. As to claim 14, Rienmueller et al. teaches a method for establishing breath-holding reproducibility in a patient for the delivery of radiation therapy according to claim 10, the method including repeating the step of suspending patient ventilation at a specific air flow direction and lung volume as necessary to administer repeated radiation doses (col. 1, line 26-35).
- 18. Claims 15, 16, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Rienmueller et al.
- 19. As to claim 15, Rienmueller et al. teaches an apparatus for suspending ventilation in a patient and delivering radiation therapy to the patient during suspended ventilation, the apparatus comprising: an apparatus for identifying a specific air flow direction and lung volume of the patient 8; an apparatus for suspending patient ventilation at a specific air flow direction and lung volume 14; and an apparatus for administering radiation therapy during the suspension of patient ventilation 1.
- 20. As to claim 16, Rienmueller et al. teaches an apparatus for suspending ventilation in a patient and delivering radiation therapy to the patient during suspended ventilation according to claim 15 wherein the apparatus for suspending patient ventilation includes a ventilator assembly having one or more selectively operable valves fig 2.
- 21. As to claim 20, Rienmueller et al. teaches an apparatus for suspending ventilation in a patient and delivering radiation therapy to the patient during suspended

Art Unit: 3761

ventilation according to claim 15, further including a mouth piece 9 attached to the ventilator assembly.

#### Claim Rejections - 35 USC § 103

- 22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 23. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rienmueller et al. in view of Donaldson et al. 5,950,631
- 24. As to claim 8, Rienmueller et al. teaches the method for delivery radiation therapy to a patient during suspended ventilation according to claim 1. It should be noted that Rienmueller et al. fails to teach the step of applying to the patient a mechanical device for attachment to the patient's nose for temporarily halting air passage therethrough. However Donaldson et al. does teach the step of applying to the patient a mechanical device for attachment to the patient's nose 70 for temporarily halting air passage therethrough. Therefore it would have been obvious to one of ordinary skill in the art to modify the method of Rienmueller et al. to include the step of applying to the patient a mechanical device for attachment to the patient's nose to prevent breathing through the nose affecting treatment.
- 25. Claims 17, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rienmueller et al. in view of Beran 4,815,459.

Application/Control Number: 09/424,431

Art Unit: 3761

26. As to claim 17, Rienmueller et al. teaches an apparatus for suspending ventilation in a patient and delivering radiation therapy to the patient during suspended ventilation according to claim 15 wherein the ventilator assembly fig. 2includes a first one-way valve 14. It should be noted that Rienmueller et al. fails to teach a t-connector, a second one-way valve, and a pneumotach. However, Beran does teach a t-connector 12, a second one-way valve (col. 4, line 13), and a pneumotach 50. Therefore it would have been obvious to one of ordinary skill in the art to modify the apparatus of Rienmueller et al. to include the assembly of Beran to measure air pressure and flow rate of the patient.

Page 7

- 27. As to claim 18, the combination of Rienmueller/Beran teaches an apparatus for suspending ventilation in a patient and delivering radiation therapy to the patient during suspended ventilation according to claim 17 further including a computer 5 and 13, the first one-way valve, and the pneumotach being operably associated with the computer.
- 28. As to claim 19, the combination of Rienmueller/Beran teaches an apparatus for suspending ventilation in a patient and delivering radiation therapy to the patient during suspended ventilation according to claim 18 further including a monitor 6 for providing a readout of cyclical lung volume trace an target respiration level while the patient is breathing, the monitor being operably attached to the computer.

Application/Control Number: 09/424,431

Art Unit: 3761

### Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (703) 305-3285. The examiner can normally be reached on Mon.-Fri. 8:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Weiss can be reached on (703) 308-2702. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 306-4520 for regular communications and (703) 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

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March 19, 2002

John G. Weiss

Supervisory Patent Examiner

Page 8

Group 3700